4-30-93

EFFICACY REVIEW

DATE: IN 2-22-93 OUT 4-30-93

FILE OR REG. NO. 56575-5

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED January 29, 1993

DATE OF SUBMISSION January 26, 1993

DATE SUBMISSION ACCEPTED

TYPE PRODUCT(S): (I,)D, H, F, N, R, S

DATA ACCESSION NO(S). 426492-01;D188284;S435522;Case#120110;AC:310

PRODUCT MGR. NO. 10-Mountfort/Waldo

PRODUCT NAME(S) Natrapel® Spray

COMPANY NAME Tender Corporation

SUBMISSION PURPOSE Provide performance data in support of "me-too" registration on horses for repellency of stable flies, horn flies and Aedes spp. mosquitoes.

CHEMICAL & FORMULATION Oil of citronella 10.6%

(8.3 lbs./gal. liquid spray, ready-to-use)

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 426492-01, having been obtained from standard field testing conducted according to a protocol which meets the requirements of 95-8(a)(1)-(5) on p. 255, (5)(vi) on p. 256 and (7) and (8) on p. 258, and the standard of 95-8(b)(2)(iii) on p. 261 of the Product Performance Guidelines, are adequate to support claims for repellency of mosquitoes when the subject product is applied as a whole-body spray to horses according to label directions. These data are also adequate to support a claim for satisfactory reduction in annoyance from horn fly, Haematobia irritans, for up to 4 hours when 2 applications are made per day on 2 consecutive days. These data are not adequate to support an unqualified repellency claim for horn fly unless continued use reduces infestation by a minimum of 90% (see last sentence of 95-8(b)(2)(iii)).

Furthermore, these data do not support any claim for stable fly, Stomoxys calcitrans, since there was no difference in rates of feeding between treated and controls in any of the 3 types of applications, namely single treatment, 2 treatments per day for 1 day and 2 treatments per day for 2 consecutive days. (continued)

21901 CITRONELLA

Because these are the only biting flies for which performance data have been submitted for this formulation, to the best of our knowledge, this lack of performance raises suspicions about the general fly claim, and not only for the subject product but also the other active registration using the same formulation (EPA Reg. No. 56575-6). Therefore, the registrant must amend the label claim to read either "non-biting flies" or provide data in support of activity against specific biting flies they desire to claim on the label. At the present time, this claim should be limited to horn flies.

According to REFS, the only active products with citronella as the sole active ingredient are not intended for use on horses but rather for application to "human body, hair, clothing or footwear while being worn". This is also true of the registrant's 2 cancelled products, EPA Reg. Nos. 56575-3 and 56575-4. All of the other cancelled registrations which claim gnats and mosquitoes are nearly 100% citronella and are also not intended for use on horses to repel biting flies. It is our opinion that citronella by itself lacks sufficient biological activity to repel larger biting flies. This is borne out by the fact that according to REFS, the 3 active products containing citronella and labeled for stable fly all have several other active ingredients, many of them Stabilene™. So do the 8 inactive citronella products labeled for stable fly, 4 of them with Stabilene™ and all but 3 of them with other MGK repellents. The 3 without MGK repellents all contain Stabilene™ and vice versa. One product contains both. Finally, there are no data in 'Insecticide & Acaricide Tests', volumes 2 through 17, which would support a stable fly claim for citronella as the lone active.

RL Vern L. McFarland, IRB

2